

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Sheet 1 of 3

| | |
|------------------------|-------------|
| Application Number | |
| Filing Date | |
| First Named Inventor | Lu, Natalie |
| Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 27-8915 |

| U. S. PATENT DOCUMENTS | | | | | |
|----------------------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | |
| SH ↓ ↓ ↓ ↓ ↓ ↓ | | US- 3,888,866 | 06/10/1975 | Leute et al. | |
| | | US- 4,197,237 | 04/08/1980 | Leute et al. | |
| | | US- 4,207,307 | 06/10/1980 | Kaul et al. | |
| | | US- 5,808,074 | 09/15/1998 | Gowda et al. | |
| | | US- 6,174,723 - B1 | 01/16/2001 | Yugawa et al. | |
| | | US- 6,271,381 - B1 | 10/07/2001 | Yugawa et al. | |
| | | US- 6,541,004 - B1 | 04/01/2003 | Scherrmann et al. | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|---|--------------------------------|--|--|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| | | | |
|--------------------|----------------|-----------------|------------|
| Examiner Signature | /Shafiqul Haq/ | Date Considered | 06/07/2006 |
|--------------------|----------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|---|---|--------------------------|----------------|------------------------|-----------|
| Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Complete if Known | | | |
| | | Application Number | | | |
| | | Filing Date | | | |
| | | First Named Inventor | Lu, Natalie T. | | |
| | | Art Unit | | | |
| | | Examiner Name | | | |
| Sheet | 2 | of | 3 | Attorney Docket Number | 27 - 8915 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| SH | | LU, NATALIE, "Distinguishing Crack Use From Powder Cocaine: Identification of Unique Pyrolysis Products from Crack Use In Urine", April 26 - 30, 1999. | |
| | | JACOB, PEYTON III, et al., "A pyrolysis Product, Anhydroecgonine Methyl Ester (Methylecgonidine), is in the Urine of Cocaine Smokers", Journal of Analytical Toxicology, Vol.14, Nov/Dec 1990. | |
| | | CONE, EDWARD J., et al., "simultaneous Measurement of Cocaine, Cocaethylene, Their Metabolites, and "Crack" Pyrolysis Products by Gas Chromatography-Mass Spectrometry", 1994, pp 1299-1305, Vol.40/7 | |
| | | LEVINE, BARRY, et al., "Stability of Ecgonine Methyl Ester in Postmortem Urine Specimens", Journal of Forensic Sciences, JFSCA, Vol. 41, No. 1, January 1996, pp 126-128. | |
| | | RILEY, K. JACK, NATALIE T. LU, ET AL., "Monitoring the Crack Epidemic through Urine Testing: Establishment of Routine Detection Methods", Addiction Biology, 2001, pp 83 - 95. | |
| | | PASCAL, KINTZ, et al., "Testing Human Hair and Urine for Anhydroecgonine Methyl Ester, a Pyrolysis Product of Cocaine", Journal of Analytical Toxicology, Vol. 19, October 1995 pp479-482. | |
| | | CONE, EDWARD, "Validity of Commercial Urine Cocaine Metabolite Assays: III. Evaluation of an Enzyme-Linked Immunosorbent | |
| | | Assay (ELISA) for Detection of Cocaine and Cocaine Metabolite" Journal of Forensic Sciences, Vol. 34, No. 4, July 1989, pp991-995. | |
| | | CONE, EDWARD, et al., "Validity Testing of Commercial Urine Cocaine Metabolite Assays: IV. Evaluation of the EMIT d.a.u. Cocaine Metabolite Assay in Quantitative Mode for Detection | |
| ✓ | | of Cocaine Metabolite, Journal of Forensic Sciences, Vol. 35, No. 4, July 1990, pp. 786 - 791. | |

| | | | |
|--------------------|----------------|-----------------|------------|
| Examiner Signature | /Shafiqul Haq/ | Date Considered | 06/07/2006 |
|--------------------|----------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|---|---|--------------------------|---------------|------------------------|-----------|
| Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Complete if Known | | | |
| | | Application Number | | | |
| | | Filing Date | | | |
| | | First Named Inventor | Lu Natalie T. | | |
| | | Art Unit | | | |
| | | Examiner Name | | | |
| Sheet | 3 | of | 3 | Attorney Docket Number | 27 - 8915 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| SH | | ROMBERG, ROBERT W. and Past, M.R., "Reanalysis of Forensic Urine Specimens Containing Benzoyllecgonine and THC-COOH", | |
| | | Journal of Forensic Sciences, Vol. 39, No. 2, March 1994 pp. 479-485. | |
| | | JEFFCOAT, ROBERT A., et. al., "Cocaine Disposition in Humans After Intravenous Injection, Nasal Insufflation (Snorting), or Smoking", Drug Metabolism and Disposition, Vol. 17, No. 2, 1989 pp. 153-159. | |
| ↓ | | MARTINEZ, FRANCISCA, et. al., "Cocaine Metabolite (Benzoyllecgonine) in Hair and Urine of Drug Users, "Journal of Analytical Toxicology, Vol. 17, May/June 1993, pp. 138-142. | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

| | | | |
|--------------------|----------------|-----------------|------------|
| Examiner Signature | /Shafiqul Haq/ | Date Considered | 06/07/2006 |
|--------------------|----------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.